

May 24, 1999  
8048 W. Potomac Avenue  
Milwaukee, WI 53218-4561  
Phone: (414) 578-0952

Dockets Management Branch (HFA-305) 56 '99 MAY 28 A9:10  
Docket No. 98-N-1265  
Food and Drug Administration  
5600 Fishers Lane Room 1061  
Rockville, MD 20857

I am writing as a private citizen to say that I strongly OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular I object to the definition of "inordinate amount" which restricts the availability and the right to obtain necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

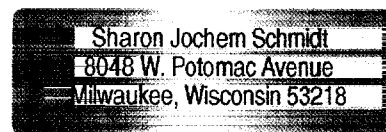
I live with severe allergies to many medications and specifically with severe allergies to the preservatives used in all liquid injectable medications used to administer intramuscular (IM) Vitamin B12, such as cyanocobalamin and hydroxocobalamin. I have reactions to the preservatives in these medications which include, but are not limited to, shortness of breath, throat closing, severe migraine headaches, inability to focus my eyes and/or stay awake at all, and extreme muscular weakness and fatigue. I cannot tolerate these reactions safely and survive taking my needed Vitamin B12 injections to counter severe, debilitating fatigue.

College Pharmacy in Colorado Springs, CO is the only pharmacy my physician and I have ever found which is willing and able to compound for me preservative-free hydroxycobalamin in lcc injectable vials and ship it to me for home injection as prescribed by my legally licensed medical doctor. These injections are medically necessary for me to maintain physical function and health.

If the FDA were to take away the rights of me, my physician and College Pharmacy to provide these safe, medically necessary medications, you would be interfering with the ONLY WAY I have access to safe medical treatment. You would be interfering with my rights as a U.S. citizen to freedom of choice in my health care.

I do not believe the FDA or any other government agency has the right to limit legally prescribed medications or treatment, no matter where the medications or treatment are purchased within the United States. Large pharmaceutical companies ship medications over state lines every day in this country, to both pharmacies and consumers. But large pharmaceutical companies do not cater to or care about special needs patients such as myself. I asked both Walgreens and Osco Drugs, with all of their pharmaceutical company access, to come up with preservative-free hydroxycobalamin for me and both said there was no such product available to help me. Small, independent compounding pharmacies, such as College Pharmacy, cater to and make safe, legal life-saving medications for special needs patients, and then ship them to us. They should continue to have the legal right to do so. The public demands this right.

98N-1265  
*Sincerely,*  
*Sharon M. Jochem Schmidt*



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Sharon Jochem Schmidt  
8048 W. Potomac Avenue  
Milwaukee, Wisconsin 53218



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